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EXAMINER	
KOHARSKI, CHRISTOPHER	
ART UNIT	PAPER NUMBER
3763	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,816	LERNER, EDUARD N.	
	Examiner	Art Unit	
	CHRISTOPHER D. KOHARSKI	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4 and 7-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4 and 7-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

The Examiner acknowledges the reply filed 11/21/2008 in which claims 3-4, and 8-12 were amended and new claims 13-25 were added. Currently claims 3-4 and 7-25 are pending for examination in this application. The Examiner also acknowledges the amendments to the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 7-10, 12, 15-16, 20-21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Feiring (USPN5,236,413). Feiring discloses a method and apparatus for inducing the permeation of medication into internal tissue.

Regarding claims 3, 7-10, 12, 15-16, 20-21, and 24, Feiring discloses an apparatus (Figure 1) capable of enhanced and controlled delivery of a biologically active agent into the spinal structures and/or the brain of a mammal, particularly a human being that circumvents the blood brain barrier, comprising: an agent drug delivery device(Figures 3-3a, 14) implantable via catheter (10) to the epidural space of the mammal, a drug reservoir (inside space of 14) with impermeable parts (wall 14, 12a) and permeable parts (pores 30), a donor iontophoresis electrode (28) also implantable to the epidural space of the mammal, a receptor iontophoresis (13) electrode that is

constructed and capable of being arranged to be positioned at a determined internal or external position of the mammal's body (Figure 4) but in complementary energy gradient positioning to the first electrode, means for providing a potential gradient (44) so that delivery of the biologically active agent is delivered in a direction from said first electrode means directly into the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, and thereby delivering said biologically active agent to the spinal structures and/or to the brain of said mammal (Figures 1-4, cols 1-2).

Claim Rejections - 35 USC § 102

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Shapland et al. (USPN5,807,306). Shapland et al. discloses a polymer matrix drug delivery device.

Regarding claim 4, Shapland et al. discloses an apparatus (Figure 10) capable of enhanced and controlled delivery of a biologically active agent into the spinal structures and/or the brain of a mammal that circumvents the blood brain barrier, comprising: an agent drug delivery device (110) implanted via catheter and capable of being placed in the the epidural space of a mammal; a phonophoresis device (108) implanted to the epidural space of the mammal; a power source to deliver a potential gradient so that delivery of the biologically active agent is accomplished in a direction from said phonophoresis device directly into the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, and thereby delivering said biologically active agent to the spinal structures and/or to the brain of said mammal wherein the phonophoresis device includes an impermeable part (tube under 108), a

drug transfer (part fluid within 112, or 112) and a piezoelectric transducer (108) between the impermeable part and the drug transfer part to induce agent delivery in a direction from the impermeable part to a drug transfer surface (110) of the drug transfer part (Figure 10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 13 are rejected under 35 U.S.C 103(a) as being unpatentable over Feiring (USPN5,236,413) in view of Rosenthal et al. (USPN6,524,274). Feiring meets the claim limitations as described above except for the swelling drug reservoir.

However, Rosenthal et al. teaches triggered release hydrogel delivery system.

Regarding claims 11 and 13, Rosenthal et al. teaches a catheter (51) with an expandable balloon assembly (54, 55) on the distal end thereof, in which a pH swellable

(col 3, ln 35-60) hydrogel layer is present as a release substrate for therapeutic agents (Figures 1-7c, cols 1-2).

At the time of the invention, it would have been obvious to use the balloon assembly of Rosenthal et al. with the system of Feiring in order to have a sustained release substrate for therapeutic agents providing a controller release time frame for treatment. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Rosenthal et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 14, 17 and 24-25 are rejected under 35 U.S.C 103(a) as being unpatentable over Feiring (USPN5,236,413) (or Feiring (USPN5,236,413) in view of Rosenthal et al. (USPN6,524,274) in view of Shapland et al. (USPN5,807,306). Feiring (of the modified Feiring) meets the claim limitations as described above except for the specific drug transfer and impermeable part limitations.

However, Shapland et al. teaches a polymer matrix delivery device.

Regarding claims 14, 17 and 24-25, Shapland et al. teaches an apparatus (Figure 9) capable of enhanced and controlled delivery of a biologically active agent into the spinal structures and/or the brain of a mammal that circumvents the blood brain barrier, comprising: an agent drug delivery device (90) implanted via catheter and capable of being placed in the the epidural space of a mammal; a iontophoresis device (100) implanted to the epidural space of the mammal; a power source to deliver a

potential gradient so that delivery of the biologically active agent is accomplished in a direction from said iontonphoresis device directly into the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, further wherein the device includes an impermeable part (98), a drug transfer (part fluid within 92, or 92) and a iontophoresis conductor (100) between the impermeable part and the drug transfer part to induce agent delivery in a direction from the impermeable part to a drug transfer surface (94) of the drug transfer part (Figures 9A-9B).

At the time of the invention, it would have been obvious to include the drug delivery structures of Shapland et al. to the system of Feiring (or modified Feiring) in order to promote controlled drug delivery via the external hydrogel layer. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Shapland et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 18-19, are rejected under 35 U.S.C 103(a) as being unpatentable over in Feiring (USPN5,236,413) view of Lew et al. (USPN5,084,006). Feiring meets the claim limitations as described above except for the biosensor.

However, Lew et al. teaches an iontophoresis delivery device.

Regarding claims 18-19, Lew et al. teaches an iontophoresis drug delivery system (Figure 1) with a control circuit (19) that is provided with a bio-sensor (col 7, ln 50-67) that is used for a bio-feedback system (col 8, 1-20) and drug dosage management.

At the time of the invention, it would have been obvious to incorporate the sensor and control system of Lew et al. to the system of Feiring in order to accurately control and treat a patient via an automated system. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Lew et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 22-23, are rejected under 35 U.S.C 103(a) as being unpatentable over Feiring (USPN5,236,413).

Regarding claims 22-23, Feiring discloses the claimed invention except for the specific electrode materials. Lacking specific criticality for the claimed materials, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the electrodes of the materials as claimed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).*

Response to Arguments

Applicant's arguments filed 11/21/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the device of Feiring (USPN5,236,413) does not disclose the claim limitations of being implanted into the epidural space of a mammal and does not disclose a drug reservoir, impermeable part and electroconductive member.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that claim limitation of implanting the device within a mammal in intended use. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). Therefore the Examiner asserts that the device of Feiring is capable of being implanted into the epidural space of a mammal. Regarding the drug reservoir, impermeable part and electroconductive member, the Examiner asserts that the Feiring reference discloses these elements as described above. Applicant's claims do not reference the specific location, shape, size or specific aspects that overcome the prior art.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

The Examiner suggests further clarification of the different drug delivery elements with specific reference to their spatial location with respect to each other as shown in Figures 2A-2B.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 2/02/2009

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763